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APPLICATION NO.	FIL	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/839,949	0	4/19/2001	Jean-Louis Excoffier	01-02 US	4507
23693	7590	06/19/2003			
Varian Inc.				EXAMI	NER
Legal Depar 3120 Hanser		02		MAHATAN,	CHANNING
Palo Alto, C	A 94304			ART UNIT	PAPER NUMBER
				1631	10
				DATE MAILED: 06/19/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

1	· · ·	Application No.	Applicant(s)	
•	. •		EXCOFFIER, JEAN-LOUIS	
Office 'Andien Commons		09/839,949		
	Office Action Summary	Examiner	Art Unit	
	The MAILING DATE of this communication app	Channing S. Mahatan	1631	
Period fo		gears on the cover sheet with the c	,	
THE N - Exter after - If the - If NO - Failui - Any n earne	ORTENED STATUTORY PERIOD FOR REPLINATION. MAILING DATE OF THIS COMMUNICATION. Isions of time may be available under the provisions of 37 CFR 1.1 (SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period for the to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing dipatent term adjustment. See 37 CFR 1.704(b).	I36(a). In no event, however, may a reply be till by within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	nely filed /s will be considered timely. n the mailing date of this communication. ED (35 U.S.C. § 133).	
Status 1)⊠	Responsive to communication(s) filed on <u>02</u>	April 2003 .		
2a)⊠	·	nis action is non-final.		
3)□	Since this application is in condition for allow		prosecution as to the merits is	
,	closed in accordance with the practice under	Ex parte Quayle, 1935 C.D. 11,	453 O.G. 213.	
•	on of Claims	•	•	
-	Claim(s) 1-56 is/are pending in the applicatio			
	4a) Of the above claim(s) 30-42 is/are withdra	wn from consideration.		
, —	Claim(s) is/are allowed.			
	Claim(s) <u>1-29 and 43-56</u> is/are rejected.			
7)	Claim(s) is/are objected to.	t the second		
-	Claim(s) <u>1-56</u> are subject to restriction and/or	election requirement.		
	ion Papers The specification is objected to by the Examin	er		
,	The specification is objected to by the Examination The drawing(s) filed on is/are: a) ☐ acception		aminer.	
10)	Applicant may not request that any objection to the			
11)[\fi	The proposed drawing correction filed on <u>02 A</u>			
11/63	If approved, corrected drawings are required in re			
12)	The oath or declaration is objected to by the E			
	under 35 U.S.C. §§ 119 and 120			
	Acknowledgment is made of a claim for foreig	gn priority under 35 U.S.C. § 119	(a)-(d) or (f).	
1	☐ All b)☐ Some * c)☐ None of:		,	
-/	1. Certified copies of the priority documer	nts have been received.		
	2. Certified copies of the priority documents have been received in Application No			
*	Copies of the certified copies of the pri application from the International B See the attached detailed Office action for a lis	ority documents have been recei Bureau (PCT Rule 17.2(a)).	ved in this National Stage	
14)	Acknowledgment is made of a claim for domes	stic priority under 35 U.S.C. § 119	(e) (to a provisional application).	
	a) The translation of the foreign language p Acknowledgment is made of a claim for dome	rovisional application has been re	eceived.	
Attachme	• •	-	. (DTO 440) B ()	
2) Noti	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449)	, <u>—</u>	ary (PTO-413) Paper No(s) al Patent Application (PTO-152)	
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Approved for use through 10/31/2002. OMB 0651-0031
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NFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known		
Application Number	09/839,939	呈
Filing Date	April 19, 2001	C
First Named Inventor	Jean-Louis Excoffier	
Group Art Unit	1632	
Examiner Name		
Attorney Docket Number	01-02 US	නි
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		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		21
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or-country where published.		12
	<u> </u>	Internet Website InfoMetrix located at http://www.infometrix.com		
	1	V 197	į	<u> </u>
- Chm	2	Article by EXCOFFIER, et al., entitled "Faster Quantitative Evaluation of High-Performance Liquid Chromatography - Ultraviolet Diode-Array Data by Multicomponent Analysis", published in Journal of Chromatography, 631, (1993), pages 15-21.	H VEIN	
V	3	Article by OEFNER, et al., entitled "Comparative DNA Sequence by Denturing High Performance Liquid Chromatography (DHPLC)", published in American Journal of Human Genetics 57 (1995) A266.		5
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Examiner Signature C. Mul 4	Date Considered	pure 12,2003
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP	609. Draw line throu	gir citation if not in conformance and n

considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments in Paper No. 8, filed 02 April 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-29 and 43-56. Claims 30-42 remain withdrawn.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18 and 49-53 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter as necessitated by amendment.

NON-STATUTORY SUBJECT MATTER

Claims 1-18, 44, 45, and 49-53 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a "method for analyzing chromatograms".

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M.P.E.P. section entitled "Nonstatutory Subject Matter" (pages 2100-12, Columns 1-2) states:

Claims to processes that do nothing more than solve mathematical problems or manipulate abstract ideas or concepts are more complex to analyze and are addressed below. If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 U.S.P.Q.2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

Further, M.P.E.P. section entitled "Statutory Process Claims" (page 2100-15, Column 1-2) states:

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. Schrader, 22 F.3d at 296, 30 U.S.P.Q.2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See Diamond v. Diehr, 450 U.S. at 183-84, 209 U.S.P.Q. at 6 (quoting Cochrane v. Deener, 94 U.S. 780, 787-88 (1877)) ("A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subjectmatter to be transformed and reduced to a different state or thing.... The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence."). See also Alappat, 33 F.3d at 1543, 31 U.S.P.O.2d at 1556-57 (quoting Diamond v. Diehr, 450 U.S. at 192, 209 U.S.P.Q. at 10). See also id. at 1569, 31 U.S.P.Q.2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing O 'Reilly v. Morse, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

The computation steps/processes of claims 1-18 and 49-53 are merely "mental" processes of performing mathematical operations (manipulation of numbers) applied to a computer. The claims do not recite any concrete or tangible results; therefore the claims do not recite statutory subject matter. For example, instant claim 1 comprises the steps of receiving data, adjusting it, reducing it, and comparing it to another set of data. It should be noted the "original" claims were directed to a method and system for classifying chromatograms, wherein it was presumed the resulting method and system would result in classified chromatograms.

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Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

SCOPE OF ENABLEMENT

Claims 1-29 and 43 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method, system, and computer useable medium of analyzing chromatograms, does not reasonably provide enablement for <u>all forms</u> of adjustment to chromatogram data, <u>all forms</u> of reducing chromatogram data to a data set, and <u>all equations</u> for analysis as encompassed by applicant as necessitated by amendment.

Applicant argues the claimed invention deals with methods of analyzing data (i.e. chromatogram data), which may be implemented using software, hardware, or combination of both, the nature of which is predictable. Indicating each of the steps recited in claim 1 can be practiced with predictable result. Applicant's argument is found unpersuasive and clarification of the rejection is provided for below.

The specification states "...the invention provides a method for reducing each chromatogram to a data set that can be compared to another such data set, producing a comparison result that indicates the similarity or dissimilarity of the two chromatograms" (page 3, lines 6-8), wherein specific similarity and dissimilarity equations are disclosed on pages 11 of the specification. Further, the specification states "...comparisons between different chromatograms, the positional data for peaks in different chromatograms can be analyzed consistent with each other". The following is reiterated from Paper No. 7, mailed 31 December 2002:

"Applicant's enablement is limited to "adjusting data in the first and second regions of interest comprising centering an analysis window around one or more trace features in a given region of interest" (instant claim 4); "reducing the first and second chromatogram data to the first and second data sets: comprising

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determining an integral of the first and second chromatogram data and plotting against a time axis; determining a set of time points; and forming arrays of data set values based upon the set of time points and corresponding integral values for the set of time points" (instant claim 9); "Similarity Equation" (Eq. 5); "Dissimilarity Equation" (Eq. 6); and "Distance Equation" (Eq. 7) as indicated on pages 11-12 of the specification. The original disclosure lacks guidance (other than that stated above) to perform the acts/steps of "adjusting" (i.e. centering an analysis window arbitrarily) and "reducing" (i.e. data set values based upon an arbitrary value rather than time point). The disclosure presents specific equations for determining the degree of "similarity", "dissimilarity", and "distance", however, fails to provide guidance on how to perform other "similarity", "dissimilarity", and "distance" determinations as broadly encompassed by applicants' claim language."

Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention (disclosed as a "method and system for classification of chromatograms", page 15, line 6) commensurate in scope (requiring all of the above steps) with these claims.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

Claims 1-29 and 43-56 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as necessitated by amendment.

VAGUE AND INDEFINITE

Claims 1, 19, 43, and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is "A method of analyzing chromatograms", however the claim recites a final step of "comparing the first data set and the second data set". Absent is any indication of the purpose of the instantly claimed method is to accomplish other then manipulating data (i.e. what does the final step of comparing data sets mean?). It should be note

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the "original" claims were directed to a "method for classifying chromatograms", implying a final step/set of classified chromatograms (although absent). While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state the resulting intent of the claimed method. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claim 6 (line 1) and all claims dependent therefrom recites the phrase "bad data" which is vague and indefinite. It is acknowledged that the specification (page 6, lines 16-30) describes "bad" as flawed data ("a peak that exceeds a threshold characteristic") and that a "bad data filter could be employed to determine if a particular chromatographic trace corresponds to flawed data". However, the disclosure fails to provide further meaning or limitation to the term "threshold characteristic"; absent is "the point or value above which something true or will take place and below which is not or will (take place)" which applicant regards as "bad data". Thus, given the broad concepts provided for by the disclosure, it is unclear what applicant refers to as "bad or flawed data". Clarification of the metes and bounds of this limitation, via clearer claim language, is required.

Claim 3 is confusing wherein the claim indicates the steps of <u>identifying</u> the first and second regions of interest in the first and second chromatogram data, respectively. Claim 1 indicates the <u>adjustment</u> of the first and second chromatogram data in a first and second region of interest, respectively. Thus, as implied by the adjustment step(s) in claim 1 the identification step(s) in claim 3 must be performed in order to adjust. Clarification of the metes and bounds, via clearer claim language is requested.

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INFORMATION DISCLOSURE STATEMENT

The information disclosure statement, Paper No. 10, was considered. However, the information disclosure statement contains a reference to an Internet website, which is lined through because the reference fails to indicate a "last updated" date. Internet websites are continuously updated and thus, the information publicly available on the website cannot be confirmed.

ACTION IS FINAL, NECESSITATED BY AMENDMENT

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Appropriate Correction Is Requested.

No Claims Are Allowed.

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Examiner Information

Papers related to this application may be submitted to Technical Center 1600 by facsimile

transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

in Crystal Mall 1. The faxing of such papers must conform with the notices published in the

Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is

either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-

2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be

directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703)

305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: fane 13, 2003
Examiner Initials: CSM

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